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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,923	10/30/2000	David H. Lynch	2836-E	8828

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IMMUNEX CORPORATION  
LAW DEPARTMENT  
1201 AMGEN COURT WEST  
SEATTLE, WA 98119

EXAMINER

GAMBEL, PHILLIP

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/699,923

Applicant(s)

LYNCH ET AL

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 23-25, 29, 36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15, 16 and 23-25 is/are allowed.
- 6) ☒ Claim(s) 29, 36 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 11/1/05 has been entered.

Applicant's amendment, filed 11/1/05, has been entered.

Claims 15-16, 29 and 38 have been amended.

Claims 1-11, 14, 17-22, 26-28, 30-35 and 37 have been canceled previously.

Claims 15, 16, 23-25, 29, 36 and 38 are pending.

2. Upon a review of the scanned filed application in eDAN, it is noted that the scanned Information Disclosure Statements do not appear to be complete (e.g., all citations do not appear to be legible).

Applicant is invited to provide copies of signed IDSs (e.g., as Exhibits) to make the scanned instant file application complete.

The examiner apologizes for any inconvenience to applicant in this matter.

3. This Office Action will be in response to applicant's amendments and arguments, filed 11/1/05.

4. Claim 38 is objected to because the proper designation of "CD34+" is "CD34<sup>+</sup>".

5. Claims 29, 36 and 38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29, 36 and 38 are indefinite in that the preamble of "an in vitro method" does not recite the purpose or intended use of the claimed invention. Therefore, the metes and bounds of the claims are ill-defined and ambiguous. For example, the relationship between the preamble and the body of the claim is not set out, nor distinctly claimed.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

#### 8. New Ground of Rejection

Claims 29, 36 and 38 are rejected under 35 U.S.C. § 102(a) as being anticipated Broxmeyer et al. (Experimental Hematology 23: 1121-1129, 1995) (see entire document) (1449; of record).

Broxmeyer et al. teach contacting CD34<sup>+</sup> enriched hemopoietic cells with flt3-L alone (or in combination with GM-CSF) for up to 21 days (see Materials and Methods and Results) in order to assay and expand hemopoietic stem or progenitor cells as well as to demonstrate the potent direct-acting stimulating / costimulating activities of flt3-L in vitro on hemopoietic stem / progenitor cells (see entire document, including Abstract and Discussion).

It is noted that the preamble language in terms of "an in vitro method" does not recite the purpose or intended use of the claimed invention.

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The body of the claim does not result in manipulative differences in the steps of claimed invention and the prior art.

Given that the starting cells population in combination with flt3-L alone (or in combination with GM-CSF) in the prior art meets the starting cell population and cytokine / growth factor recited in instant claim 29 (b); the claimed functional limitations would be inherent properties of the referenced methods to contact CD34<sup>+</sup> enriched hemopoietic stem or progenitor cells with flt3-L.

#### 9. New Ground of Rejection

Given applicant's attempt to obviate the prior art Lyman et al. (U.S. Patent No. 5,843,423) teachings via common ownership, the corresponding published international application WO 94/28381 has been provided herein in New Grounds of Rejection under both 35 USC 102 and 103(a).

Applicant's arguments, filed 11/1/05, concerning the corresponding Lyman et al. (U.S. Patent No. 5,843,423) have been fully considered but are not found convincing essentially for the reasons of record and addressed herein below in Section 10.

Claims 29, 36 and 38 are rejected under 35 U.S.C. § 102(a) as being anticipated by Lyman et al. (WO 94/28391) (see entire document) alone in view of the well known expression of CD34 on hemopoietic stem or progenitor cells at the time the invention was made, as evidenced by page 8, paragraph 2 of the instant specification.

Lyman et al. teach contacting hemopoietic stem and progenitor cells with flt3-ligand alone to expand hemopoietic stem or progenitor cells ex vivo with flt3-L, including human flt3-L to provide a cellular preparation comprising increased numbers of hemopoietic stem or progenitor cells (see entire document, including Summary of the Invention, Detailed Description of the Invention and Examples).

It is noted that the preamble language in terms of "an in vitro method" does not recite the purpose or intended use of the claimed invention.

The body of the claim does not result in manipulative differences in the steps of claimed invention and the prior art.

Given that the starting cells population in combination with flt3-L alone in the prior art meets the starting cell population and cytokine / growth factor recited in instant claim 29 (b); the claimed functional limitations would be inherent properties of the referenced methods to contact CD34<sup>+</sup> enriched hemopoietic stem or progenitor cells with flt3-L.

Although the prior art does not isolate hemopoietic stem and progenitor cells via CD34 per se, claim 38 does not recite a particular manner by which cells are enriched for the CD34<sup>+</sup> phenotype.

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It has been well known by the ordinary artisan for over a decade that hemopoietic stem and progenitor cells express CD34, as further evidenced by page 8, paragraph 2 of the instant specification. For example, stem or progenitor cells having the CD34 marker constitute only about 1% to 3% of the mononuclear cells in the bone marrow.

Therefore, the referenced hemopoietic stem and progenitor stem cells, including those described in the Summary of the Invention, Detailed Description and Examples of the prior art would be enriched for the CD34<sup>+</sup> phenotype.

10. Claims 29, 36 and 38 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lyman et al. (U.S. Patent No. 5,843,423) (see entire document) alone in view of the well known expression of CD34 on hemopoietic stem or progenitor cells at the time the invention was made, as evidenced by page 8, paragraph 2 of the instant specification.

Applicant's arguments, filed 11/1/05, have been fully considered but are not found convincing essentially for the reasons of record.

While applicant argues that the instant invention and disclosure teach generating large quantities of dendritic cells in vivo and that the prior art would not generate dendritic cells every time given an insufficient period of time to permit the cells to expand and differentiate into dendritic cells.

Here, it appears that applicant is arguing limitations not claimed in that the claims do not recite any method steps or conditions that require a certain length of time or purity of a starting hemopoietic stem populations or resulting dendritic cells.

In addition, applicant appears to raise issues under 35 USC 112, first paragraph, enablement, in that applicant appears to argue that the claims require certain time periods to achieve the claimed methods of preparing dendritic cells.

Further, it is noted that Lyman et al. is drawn to ex vivo expansion of hemopoietic cells to provide cellular preparations with increased numbers of hemopoietic cells for transplantation (e.g., see column 6, paragraphs 1-2). Therefore, the prior art did teach preparing large numbers of hemopoietic cells, which would have taken periods of time encompassed by the time periods asserted by applicant.

Lyman et al. teach contacting hemopoietic stem and progenitor cells with flt3-ligand to expand hemopoietic stem or progenitor cells ex vivo with flt3-L, including human flt3-L (see entire document, including column 5, paragraph 2, column 8, paragraph 4 and Example 4 on columns 23-24) to provide a cellular preparation comprising increased numbers of hemopoietic stem or progenitor cells (see column 6, paragraph 1 and Example 14).

It is noted that the preamble language in terms of "an in vitro method" does not recite the purpose or intended use of the claimed invention.

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The body of the claim does not result in manipulative differences in the steps of claimed invention and the prior art.

Given that the starting cells population in combination with flt3-L in the prior art meets the starting cell population and cytokine / growth factor recited in instant claim 29 (b); the claimed functional limitations would be inherent properties of the referenced methods to contact CD34<sup>+</sup> enriched hemopoietic stem or progenitor cells with flt3-L.

Although the prior art does not isolate hemopoietic stem and progenitor cells via CD34 per se, claim 38 does not recite a particular manner by which cells are enriched for the CD34<sup>+</sup> phenotype.

It has been well known by the ordinary artisan for over a decade that hemopoietic stem and progenitor cells express CD34, as further evidenced by page 8, paragraph 2 of the instant specification. For example, stem or progenitor cells having the CD34 maker constitute only about 1% to 3% of the mononuclear cells in the bone marrow.

Therefore, the referenced hemopoietic stem and progenitor stem cells, including those described in the Summary of the Invention, Detailed Description and Examples of the prior art would be enriched for the CD34<sup>+</sup> phenotype.

Applicant's arguments are not found persuasive.

#### 11. New Ground of Rejection

Claims 29, 36 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable Lyman et al. (U.S. Patent No. 5,843,423) (of record) AND / OR Lyman et al. (WO 94/28391) (1449) in view of Tsumamoto et al. (U.S. Patent No. 5,914,108) (of record) essentially for the reasons of record.

Applicant's arguments, filed 11/1/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant asserts that there was a common ownership between the present application and Lyman et al. and that a statement by applicant's representative is included in this response.

However, the statement by applicant's representative setting forth the common ownership between the instant application and the prior art Lyman et al. does not appear to be present in applicant's response filed 11/1/05.

Therefore, in the absence of the appropriate statement of common ownership at the time the invention was made, the rejection is maintained.

Applicant is invited to provide the asserted statement of common ownership.

The examiner apologizes for any inconvenience to applicant in this matter.

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Applicant's arguments and the examiner's rebuttal are essentially the same as that set forth above in Section 10.

Also, newly added Lyman et al. WO 94/28391 provides the same teachings (see entire document and Section 8 above) as the Lyman et al. (U.S. Patent No. 5,843,423) already of record.

Lyman et al. teach contacting hemopoietic stem and progenitor cells with flt-ligand to expand hemopoietic stem or progenitor cells ex vivo with flt3-L, including human flt3-L (see entire document, including column 5, paragraph 2, column 8, paragraph 4 and Example 4 on columns 23-24) to provide a cellular preparation comprising increased numbers of hemopoietic stem or progenitor cells (see column 6, paragraph 1 and Example 14).

Similarly, Lyman et al. (WO 94/23861) teach contacting hemopoietic stem and progenitor cells with flt3-ligand alone to expand hemopoietic stem or progenitor cells ex vivo with flt3-L, including human flt3-L to provide a cellular preparation comprising increased numbers of hemopoietic stem or progenitor cells (see entire document, including Summary of the Invention, Detailed Description of the Invention and Examples).

It is noted that the preamble language in terms of "an in vitro method" does not recite the purpose or intended use of the claimed invention.

The body of the claim does not result in manipulative differences in the steps of claimed invention and the prior art.

Lyman et al. differs from the claimed methods by not disclosing the well known expression of CD34 on hemopoietic stem cells. Given that the starting cells population in combination with flt3-L and GM-CSF in the prior art meets the starting cell population and cytokines / growth factors recited in the instant claim; the claimed functional limitations would be intrinsic properties of the referenced methods to contact hemopoietic stem or progenitor cells with flt3-L and GM-CSF.

It has been well known by the ordinary artisan for over a decade that hemopoietic stem and progenitor cells express CD34, and that various means for known and used to select such CD34<sup>+</sup> hemopoietic stem cells as taught by Tsukamoto et al. (see entire document, including Summary of the Invention and Description of the Specific Embodiments).

In order to increase the efficiency and, in turn, the efficacy of hemopoietic stem cell populations, one of ordinary skill in the art at the time the invention was made would have been motivated to employ the methods of isolating CD34<sup>+</sup> hemopoietic stem and progenitor cells as taught by Tsukamoto et al. prior to their exposure to flt3 ligand (and GM-CSF) in the methods taught by Lyman et al. for various therapeutic modalities associated with the use of hemopoietic stem cells, including transplantation of such cells known and practiced at the time the invention was made (see the Detailed Description in both Lyman et al. and Tsukamoto et al.). From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.



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Applicant's arguments are not found persuasive.

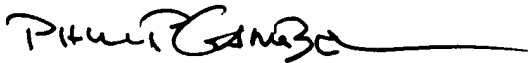
12. As indicated previously, it appears that claims 15-16 and 23-25 appear to be free of the prior art, given the "consisting" language and "exposing dendritic cells to an antigen".

13. No claim allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, Ph.D., J.D.  
Primary Examiner  
Technology Center 1600  
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